ACCESS / CDER

Chemistry, Manufacturing and Control

ESD Template

Last Update: October 27, 1999

Prepared By The University of Maryland Database Design Group

The following are the specifications for a text file that contains information related to the Chemistry, Manufacturing and Control(CMC) Sections of an Abbreviated New Drug Application. It allows this data to be automatically entered into the CMC database so it is available for examination by FDA reviewers using the CMC ACCESS/CDER database tools.

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|BEGIN SUBMISSION SECTION|

This section contains the basic information about the applicant and the submission. The information in this section should be taken directly from the PHS 356H form.

::APPLICANT ID::
Required
The unique identification code of the company sponsoring the submission.
3 Char.

::ANDA NO::
Optional
If Submission Type is anything except an original submission, enter the ANDA number for the drug. If original submission enter (N/A).
8 Char.

::SUBMISSION TYPE::
Required
Specify either Original, Amendment or Supplement.
15 Char.

::SUBMISSION NO.::
Required
Applicant assigned ID that uniquely identifies this submission. If there is not an internal company ID, enter any ID. The ID is used only as a link to other sections of the database.
10 Char.

::SUBMISSION DATE::
Required
Date from the PHS 356H form.
MM/DD/YYYY.

::BATCH SIZE DEFINITION::
Required
Briefly describe how the manufacturing company defines batch size throughout this submission.
255 Char.

::MANUFACTURE DATE DEFINITION::
Required
Describe how the company defines the batch manufacture date throughout this submission.
255 Char.

|BEGIN AUXILIARY FIRM INFORMATION|

Optional Block: Information on auxiliary firms that are involved in the manufacture of the drug. Include drug substance manufacturers and test labs. Address requirements are the same as for the applicant address. Include the Begin and End statement each time the block is repeated.

::AUXILIARY FIRM ID::
Required
An identifier which uniquely identifies each of the auxiliary firms in this application. If there is not an internal company ID, enter any ID. The ID is used only as a link to other sections of the database. (AFID-001)

7 Char.

::AUXILIARY FIRM::
Required
Name of auxiliary firm.
80 Char.

::CONTACT PERSON::
Required
The name of the contact at the auxiliary firm.
30 Char.

::TITLE::
Required
Title of contact person.
255 Char.

::STREET ADDRESS 1::
Optional
Building name and street address.
80 Char.

::STREET ADDRESS 2::
Optional
Building name and street address (continued).
80 Char.

::CITY::
Optional
City name of auxiliary firm’s correspondence address.
30 Char.

::STATE::
Optional
State (or corresponding foreign region) of auxiliary firm’s correspondence address.
30 Char.

::POSTAL CODE::
Optional
Postal (ZIP) code of auxiliary firm’s correspondence address.
15 Char.

::COUNTRY::
Optional
Country of auxiliary firm’s correspondence address.
30 Char.

::TELEPHONE NO::
Required
Telephone number of auxiliary firm.
30 Char.

::FAX NO::

Required
Fax number of auxiliary firm.
30 Char.

|END AUXILIARY FIRM INFORMATION|

::US AGENT::
Optional
If an Auxiliary Firm functions as a US Agent, include its name. Use the same name that is listed in the Auxiliary Firm Identification block above.
80 Char.

|BEGIN DRUG DESCRIPTION|

::ESTABLISHED/GENERIC NAME::
Required
USP/USAN drug product name.
80 Char.

::NDA ID::
Required
The New Drug Application number of the innovator product listed in the Orange Book.
8 Char.

::DOSAGE FORM::
Required
One of the following - Tablet, Capsule, Injectable etc. To be completed from official FDA list.
30 Char.

::RX OR OTC::
Indication of whether the drug is prescription or over the counter.
3 Char.

::INNOVATOR PRODUCT::
Required
The proprietary name of the approved drug.
80 Char.

::INNOVATOR COMPANY::
Required
Name of the company producing the drug.
80 Char.

::PHARMACOLOGICAL CLASS::
Required
USAN or Label.
255 Char.

::CHEMICAL CLASS::
Required
USAN or Label.
255 Char.

::CHEMICAL NAME::
Required
USAN Chemical name.
255 Char.

::PATENT EXPIRATION DATE::
Required
Expiration date of the patent from the Orange Book.
MM/DD/YYYY

|END DRUG DESCRIPTION|

|BEGIN SPECIFICATION|

::SPECIFICATION NO::
Required
Unique identifier for this specification
Integer

::SPECIFICATION TYPE::
Required
Indicates whether the specification applies to Raw Material, In-Process, Release or Stability Test.
15 Char.

::PARAMETER::
Required
The parameter being tested.
80 Char.

::SPECIFICATION::
Required
A general description of the allowable limits of the parameter being tested.
255 Char.

::METHOD::
Required
The method used to determine the value(s) of the parameter being tested. Standard USP name or other standard name may be used. Describe the method if it is not standard.
255 Char.

::COMMENTS::
Optional
Any additional information.
255 Char.

|END SPECIFICATION|

|BEGIN EQUIPMENT SPECIFICATION|

Refer to Appendix B when completing the Equipment Type and Description fields.

::EQUIPMENT NO::
Required

An identifying number for this piece of equipment.
3 Char.

::EQUIPMENT TYPE::
Required
Refer to list in Appendix B.
80 Char.

::DESCRIPTION::
Required
Include values for all the descriptors in Appendix B under the corresponding equipment type.
255 Char.

::MANUFACTURER::
Required
Manufacturer of this piece of equipment.
80 Char.

::MODEL::
Required
Model name/number of this piece of equipment.
255 Char.

|END EQUIPMENT SPECIFICATION|

|BEGIN RESPONSIBLE OFFICIAL|

This block includes the name of the official to whom all communications should be addressed. Address requirements are the same as for the applicant address.

::NAME::
Required
The sign-off name on the PHS 356H.
30 Char.

::TITLE::
Required
Title of Responsible Officer.
255 Char.

::STREET ADDRESS 1::
Optional
Building name and street address.
80 Char.

::STREET ADDRESS 2::
Optional
Building name and street address (continued).
80 Char.

::CITY::
Optional
City name of official’s correspondence address.

30 Char.

::STATE::
Optional
State (or corresponding foreign region) of official's correspondence address.
30 Char.

::POSTAL CODE::
Optional
Postal (ZIP) code of official's correspondence address.
15 Char.

::COUNTRY::
Optional
Country of official's correspondence address.
30 Char.

::TELEPHONE NO::
Required
Telephone number of official.
30 Char.

::FAX NO::
Required
Fax number of official.
30 Char.

|END RESPONSIBLE OFFICIAL|

|BEGIN INGREDIENT IDENTIFICATION SECTION|

This section identifies all the ingredients in the batch/product and lists information related to them. Repeat as necessary for each ingredient. Include the Begin and End statements each time the section is repeated.

::INGREDIENT ID::
Required
Unique identifier for the ingredient.
30 Char.

::INGREDIENT NAME::
Required
The name of the ingredient.
80 Char.

::GRADE::
Required
The grade of the ingredient.
30 Char.

::FUNCTION::
Required

The function of the ingredient. Choose from: active, binder, coating, color, diluent, disintegrant, filler, flavor, gildant, or lubricant.
15 Char.

::DMF NO::
Required
30 Char.

::LOT NO::
Optional
Lot number given to the ingredient by the manufacturer of the ingredient.
30 Char.

::DRUG SUBSTANCE MANUFACTURER::
Required
An identifier which uniquely identifies the auxiliary firm responsible for manufacturing this ingredient. Enter N/A if this ingredient is manufactured internally.
7 Char.

::MANUFACTURER LOT NO::
Required
Lot number given to the ingredient by the company manufacturing the generic product. If there is no unique, company assigned lot number, enter the value of ::Lot No:: above.
30 Char.

|BEGIN RAW MATERIAL TEST|

::TEST ID::
Required
Unique identifier for this test.
10 Char.

::SPECIFICATION NO::
Required
Unique identifier for the specification
Integer

::TEST DATE::
Required
Date the test began.
MM/DD/YYYY

::TESTING LABORATORY::
Required
Auxiliary Firm ID of the facility where the test was conducted.
7 Char.

::RESULT::
Required
The result of the test applied to the batch. If this is a blank batch type, no results are required.
255 Char.

::COMMENTS::
Optional
Any additional information.
255 Char.

|END RAW MATERIAL TEST|

|END INGREDIENT IDENTIFICATION SECTION|

|BEGIN COMPONENT DESCRIPTION|

*This block will describe all the components that may be used in the packaging of your product. Repeat this block as necessary for each component that appears in **any** of the packages. **If the same component is used in multiple packages, only list the component once. If the same component has two or more different uses that cause it to have different qualities (such as width or volume), each use should be listed in a different block, with its own Component ID**. Include the Begin and End statements each time the block is repeated.*

::COMPONENT ID::
Required
Any string that uniquely identifies this particular component.
30 Char.

::COMPONENT TYPE::
Required
This indicates the type of component used.
30 Char.

*For the **Component Type**, you may choose from the following: **Container**, **Closure**, **Desiccant**, **Dunnage**, **Innerseal**, **Liner**, or **Other**.*

*For **blister packs**, use "Container" for the plastic blister pack, "Closure" for the cover, and "Other" for other things, such as additional layers for child proofing.*

*For **injectables**, use "Container" for the vial and "Closure" for the stopper.*

*For **prefilled syringes**, use "Container" for the syringe and "Closure" for the membrane. The plunger and needle would fall within "Other."*

*For **ampoules**, use "Container."*

::DMF NO::
Required
DMF Number of the component.
30 Char.

::DESCRIPTION::
Required
A general physical description of the component and its use. Include the type of material used to make the component, and the amount of the component used, if applicable.
255 Char.

*The requirements of the **Description** field depend on the **Component Type**.*

*For **containers**, include volume, height, diameter, width, and depth, as well as any additional descriptive information that may be helpful.*

*For **closure**, include height, diameter, an indication of whether or not the closure is child-resistant, and any additional descriptive information that may be helpful.*

For all other component types, a general description will suffice.

::MANUFACTURER::
Required
The name of the component manufacturer.
80 Char.

|END COMPONENT DESCRIPTION|

|BEGIN MATERIAL DESCRIPTION|

*This block will describe all the materials (both primary and alternate) that may be used in the packaging of your product. Repeat this block as necessary for each material or alternate material that appears in **any** of the packages.*

::MATERIAL ID::
Required
Any string that uniquely identifies this particular material.
30 Char.

::MATERIAL NAME::
Required
The name of the material used.
255 Char.

::MATERIAL TYPE::
Required
The type of material used, eg: Type I glass, Resin.
255 Char.

::DMF NO::
Required
The DMF number of the material used.
30 Char.

::MANUFACTURER::
Required
The name of the material manufacturer.
80 Char.

|END MATERIAL DESCRIPTION|

|BEGIN PACKAGING SPECIFICATION|

This block identifies each package and the combination of packaging components and materials that make up that package. It should be repeated as necessary to describe all the different packages used throughout the submission. Note that several different batches may go into the same package.

::PACKAGE ID::
Required
Identifier that uniquely identifies this package and the combination of packaging components in this application. If there are different package sizes or different counts, do each as a separate Packaging System Section with a separate Package ID. If there is not an internal company ID, enter any ID. The ID is used only as a link to other sections of the database. e.g. PACK-ID-001
15 Char.

::PACKAGE DESCRIPTION::
Required
A brief description of this specific package.
255 Char.

::PACKAGED OR BULK::
Required
Indication of whether this package is a marketable package or a storage package.
10 Char.

|BEGIN COMPONENT SPECIFICATION|

This block describes the components used in a specific package. Repeat as necessary to include all the components.

::COMPONENT ID::
Required
Use the Component ID from the Packaging Description.
30 Char.

::QUANTITY::
Optional
The amount of this component included in the overall package, **required for dessicant and dunnage.**
80 Char.

|BEGIN MATERIAL SPECIFICATION|

This block describes the materials used in this specific component. Repeat as necessary to include all materials that make up the component.

::MATERIAL ID::
Required
Use the Material ID from the Packaging Description.
30 Char.

::QUANTITY::
Required
The amount of this material included in the component.
80 Char.

|BEGIN ALTERNATE MATERIAL SPECIFICATION|

Optional Block: Use this block to describe any alternative materials that can or will be substituted for the above material. Repeat as necessary to describe all alternate materials.

::ALTERNATE MATERIAL ID::
Required
Use the Material ID from the Packaging Description.
30 Char.

::QUANTITY::
Required
The amount of this material included in the component.
80 Char.

|END ALTERNATE MATERIAL SPECIFICATION|

|END MATERIAL SPECIFICATION|

|END COMPONENT SPECIFICATION|

|END PACKAGING SPECIFICATION SECTION|

|BEGIN PRODUCT DESCRIPTION SECTION|

This block describes the products included in this submission. Repeat for each product. If there are multiple strengths, do each as a separate Product Description Section with a separate Product ID repeating everything in the Product Description Section for each strength of the product.

::PRODUCT ID::
Required
A unique identifier for each of the products in this application. If there are multiple strengths, do each as a separate Product Description Section with a separate Product ID. Recommend using generic name and strength, e.g. Gendrug 100mg.
10 Char.

::STRENGTH UNITS::
Required
Specify the units in which the strength of the Product is measured, eg: mg.
30 Char.

::STRENGTH::
Required
Strength of the Product, eg: 200
50 Char.

::PROPRIETARY NAME::
Optional
The proprietary or brand name of the drug product.
80 Char.

::ROUTE OF ADMINISTRATION::

Required
How the drug is administered, e.g.: Oral, Parenteral, etc.
15 Char.

::DOSAGE FORM::
Required
One of the following - Tablet, Capsule, Injectable etc. To be completed from official FDA list.
30 Char.

|BEGIN PRODUCT FORMULATION|

This block describes the ingredients in a single unit of the drug product. This is similar to the Components and Composition section. ***Repeat as necessary for each ingredient in the product.*** *Include the Begin and End statements each time the block is repeated.*

::INGREDIENT NAME::
Required
List the name of an ingredient appearing in the product.
80 Char.

::QUANTITY::
Required
Quantity of ingredient, in appropriate units (use strength units from the Product Description Section).
50 Char..

|END PRODUCT FORMULATION|

|BEGIN BATCH DESCRIPTION SECTION|

This section describes the various batches that are a part of the application. This section should be repeated for each different batch that is described in the application. Describe one batch at a time. This will include the Batch Formulation, and the Manufacturing Process. Include the Begin and End statements each time the section is repeated.

::BATCH ID::
Required
Finished product batch identifier assigned by the drug manufacturer.
10 Char.

::MANUFACTURER::
Required
The name of the company with **primary** responsibility for manufacture of this batch.
80 Char.

::MANUFACTURING SITE::
Optional
The site at which the batch was manufactured.
255 Char.

::BATCH TYPE::
Required
Valid batch types are Blank, Executed, and Bio.

30 Char.

::TOTAL BATCH WEIGHT::
Optional
Sum of the weight of all the ingredients in the actual yield of the batch, including units.
30 Char.

::MANUFACTURE DATE::
Required
Date on which the manufacture of the batch was completed.
MM/DD/YYYY.

::EXPIRATION DATE::
Required
Date on which items in the batch will expire.
MM/DD/YYYY.

::THEORETICAL YIELD::
Required
The projected output for the batch, measured in number of units, weight or volume as approproiate for the drug type. Note: **DO NOT USE COMMAS IN LARGE NUMBERS!**
Numeric.

::ACTUAL YIELD:
Required
The actual output for the batch, measured in number of units, weight or volume as approproiate for the drug type. Note: **DO NOT USE COMMAS IN LARGE NUMBERS!**
Numeric.

::BATCH QUANTITY UNITS::
Required
The units in which the ingredients of the Batch Formulation are measured. If they are measured in different units, this field should be 'N/A'
30 Char.

|BEGIN BATCH FORMULATION|

This block describes the formulation of the batch including all ingredients and total quantity used even though they may not appear in the final product. Each ingredient block describes a single ingredient in the formulation. Each ingredient in the formulation should be included as a separate ingredient. Repeat as needed for all components of the formulation. Include the Begin and End statement each time the block is repeated.

::INGREDIENT ID::
Required
Use the Ingredient ID from the Ingredient Section.
30 Char.

::QUANTITY::
Required
Quantity of ingredient, in appropriate units (use the Batch Quantity Units).
50 Char.

|END BATCH FORMULATION|

|BEGIN MANUFACTURING PROCESS|

This block provides a description of each major step in the manufacturing process including processes, ingredients, testing, and equipment. Repeat as necessary to describe each major step. Follow each step, as applicable, with the In-Process Materials, In-Process Tests, and Equipment Used blocks. These are all imbedded under a specific step. Then start with the next step. Include the Begin and End Manufacturing Process statement for each step.

::STEP NO::
Required
Sequential numeric identifier for each step, starting with 1. This number is for use in the database and need not reflect the company's step number.
Numeric.

::COMPANY STEP ID::
Optional
If the company uses another numbering series, enter the company's internal identifying code for this manufacturing step.
30 Char.

::AUXILIARY FIRM::
Optional
If an auxiliary firm was involved in this step, list the Auxiliary Firm ID from the Auxiliary Firm Information block associated with this step.
7 Char.

::STEP TYPE::
Required
Name of the process performed at this step. Enter a Step Type Name from Appendix A or an appropriate brief step name. For a sterile dosage form, enter either Terminal Sterilization, Aseptically Filled Sterilization. If both were used enter Terminal and Aseptically Filled Sterilization or specify what other method was used.
255 Char.

::DESCRIPTION::
Required
Description of the manufacturing step.
255 Char.

::DATE STEP BEGAN::
Required
Enter the date the step began.
MM/DD/YYYY

::DATE STEP ENDED::
Required
Enter the date the step ended.
MM/DD/YYYY

::MANUFACTURING SITE::
Required
Site where this step took place.
255 Char.

::INTERMEDIATE CODE NO::
Optional
An applicant defined or internal company code that was assigned to the batch at this step, and is different from Manufacturer Lot No. and the Finished Product Batch/Lot No. Use only if the company assigns a new number at this step. e.g. Blend-ID-001.
30 Char.

::INTERMEDIATE CODE NAME::
Optional
The name of the result of this step, which is associated with the Intermediate Code No., e.g. Tablet Core.
30 Char.

|BEGIN IN-PROCESS MATERIALS DESCRIPTION|

Optional Block: Include this block if any materials are added in this step. This block will show what materials were added during a specific step, and should be placed directly after the step with which it is associated. Each block describes a single material added at this step. Repeat as needed for all additional ingredients. Include the Begin and End statements each time the block is repeated.

::INGREDIENT ID::
Required
Unique identifier for the ingredient from this manufacturer. Use the same Ingredient ID as in Product Formulation If the ingredient is a combination of ingredients from a previous step, use Intermediate Code ID from the Manufacturing Process Step, e.g. AVICEL-FMC.
30 Char.

::QUANTITY::
Required
The quantity of the ingredient in the step. Use one of the standard unit identifiers, abbreviation only. e.g. kg, g, mg, etc.
80 Char.

|END IN-PROCESS MATERIALS DESCRIPTION|

|BEGIN IN-PROCESS TESTS|

Optional Block: This block describes any testing performed at this step in the manufacturing process. This block will show what tests were done during this specific step. The block should be placed directly after the step with which it is associated. If this is a blank batch type, no results are required. Begin with the first test, and repeat as needed to describe all results of each test. Include the Begin and End statements each time the block is repeated.

::TEST ID::
Required

Unique identifier for the specific test.
10 Char.

::SPECIFICATION NO::
Required
Unique identifier for the specification
Integer

::INGREDIENT ID::
Optional
Unique identifier for the ingredient - if multiple active ingredients are present in the Batch Formulation Section (and this test concerns a specific ingredient rather than the entire product), specify which ingredient is being tested.
30 Char.

::TESTING LABORATORY::
Required
Auxiliary Firm ID of the facility where the test was conducted.
7 Char.

::RESULT::
Required
The result of the test applied to the batch, If this is a blank batch type, no results are required.
255 Char.

::TEST DATE::
Required
Date on which the test took place.
MM/DD/YYYY.

::COMMENTS::
Optional
Comment on this in-process test.
255 Char.

|END IN-PROCESS TESTS|

|BEGIN EQUIPMENT DESCRIPTION|

Optional Block: This block should be filled out if equipment is used in this step. Repeat this block as necessary for each piece of equipment used.

::EQUIPMENT NO::
Required
An identifying number for this piece of equipment.
3 Char.

|END EQUIPMENT DESCRIPTION|

|END MANUFACTURING PROCESS|

|BEGIN FINISHED PRODUCT TESTS|

This block describes the tests and specifications included in the profile. Repeat as needed for all tests. Include the Begin and End statements each time the block is repeated.

::TEST ID::
Required
Unique identifier for the specific test.
10 Char.

::SPECIFICATION NO::
Required
Unique identifier for the specification
Integer

::INGREDIENT ID::
Optional
Unique identifier for the ingredient - if multiple active ingredients are present in the Batch Formulation Section (and this test concerns a specific ingredient rather than the entire product), specify which ingredient is being tested.
30 Char.

::TESTING LABORATORY::
Required
Auxiliary Firm ID of the facility where the test was conducted.
7 Char.

::TEST DATE::
Required
Date on which the test took place.
MM/DD/YYYY.

::NO UNITS TESTED::
Required
The number of units that were tested in this specific test.
Numeric.

::RESULT::
Required
The results of the test.
255 Char.

::COMMENTS::
Optional
Comments on the finished product test.
255 Char.

|END FINISHED PRODUCT TESTS|

|BEGIN BATCH PACKAGING|

This block associates the batch described above with the package(s) that will contain it. Repeat this block for every different package that will contain units of the batch.

::PACKAGE ID::
Required
Use the ID from the Packaging Specification block.
15 Char.

::PACKAGE CAPACITY::
Required
The quantity of the drug units contained in the packaging system, e.g. 500s, Bulk, Unit Dose.
30 Char.

::UNITS PACKAGED::
Required
The total number of units of this batch that are packaged in this packaging system, e.g., 50,000 units may be packaged in 500's.
Numeric.

|BEGIN STABILITY STUDY DESCRIPTION|

This block describes the studies that were conducted to evaluate the stability of the product or products in this application. Repeat as needed to describe all studies.

::STUDY ID::
Required
Unique identifier for the specific study.
10 Char.

::DESCRIPTION::
Required
A brief, written description of this study.
255 Char.

::STUDY TYPE:
Specify the type of study (Accelerated, Long Term, or Other).
30 Char.

::TEMPERATURE::
Required
Temperature at which the study was conducted, in Centigrade.
255 Char.

::LIGHT::
Required
A description of the light exposure at which the study was conducted.
255 Char.

::HUMIDITY::
Required
Relative humidity at which the study was conducted.
255 Char.

::OTHER::

Optional
Use if Study Type option is "Other". Specify name and value.
255 Char.

|BEGIN TEST PROFILE|

This block describes the tests and specifications included in the profile. Repeat as necessary to include all tests.

::TEST ID::
Required
Unique identifier for the specific test.
10 Char.

::SPECIFICATION NO::
Required
Unique identifier for the specification
Integer

::INGREDIENT ID::
Optional
Unique identifier for the ingredient - if multiple active ingredients are present in the Batch Formulation Section (and this test concerns a specific ingredient rather than the entire product), specify which ingredient is being tested.
30 Char.

::TESTING LABORATORY::
Required
Auxiliary Firm ID of the facility where the test was conducted.
7 Char.

::TIME ON STABILITY UNITS::
Required
The standardized units used for time on stability, e.g., months if stability test stations were conducted at 0, 1, and 2 months.
30 Char.

::SAMPLING TIME UNITS::
Optional
The standardized units for sampling time in all tests, if multiple samples were taken, e.g., hours if at each test station samples were measured at 0, 2, 4, and 6 hours.
30 Char.

::TIME ASSOCIATED WITH RANGE::
Optional
The time to which the specified range applies, in sampling time units, if applicable, e.g. “Dissolution” might have a Q of NLT 85% in 45 minutes, so the time would be 45.
Numeric.

::COMMENTS::
Optional

Comments on the stability test.
255 Char.

|BEGIN TEST STATION|

The stability results data are the results of the stability tests that have been conducted on the finished product. It is designed to show all the tests that have been conducted, the times the tests were conducted and the values for each test. For each test profile block, continue to repeat the test station for each of the times the test was conducted.

::TEST DATE::
Required
Date on which the test was conducted.
MM/DD/YYYY.

::TIME ON STABILITY::
Required
The amount of time for which samples have been stored under stability conditions, using the Time on Stability Units given above.
Numeric.

::NO UNITS TESTED::
Required
The number of units that were tested in this specific test.
Numeric.

::RESULT::
Optional
The results of the test, if only one sample was taken (enter N/A if multiple samples were taken, and complete the subsequent three fields).
255 Char.

::HIGH::
Optional
The high value of the test, if multiple samples were taken.
Numeric.

::LOW::
Optional
The low value of the test, if multiple samples were taken.
Numeric.

::AVERAGE::
Optional
The average value of the test, if multiple samples were taken.
Numeric.

|BEGIN INDIVIDUAL RESULT|

Optional Block: If samples were taken of different units and/or at different sampling times, you are required to complete the Individual Result Block.

::SAMPLING TIME::
Required
For studies such as dissolution that have multiple sampling times. e.g. 0, 30, or 60 (min.). The entry should be in terms of the Sampling Time Units in the Test Profile.
Numeric.

::UNIT NO::
Required
Sequential identifier for the particular unit to which this result applies, e.g., if No. Units Tested above is 6, then Unit No's will be 1, 2, 3, 4, 5, and 6 for the 6 corresponding Individual Result blocks.
Integer.

::INDIVIDUAL RESULT::
Required
The resulting value of the test of the above unit at the given sampling time.
255 Char.

|END INDIVIDUAL RESULT|

|END TEST STATION|

|END TEST PROFILE|

|END STABILITY STUDY DESCRIPTION|

|END BATCH PACKAGING|

|END BATCH DESCRIPTION SECTION|

|END PRODUCT DESCRIPTION SECTION|

|END SUBMISSION SECTION|

Appendix A - List of Step Types

Enter one of the following Step Types in the Step Type field or substitute an appropriate brief step name used in your company.

- Aseptically Filled Sterilization

- Coating

- Drying

- Dry Blending

- Dry Granulating

- Encapsulation

- Filling

- Final Blending

- Formulation

- Granulating Liquid Preparation

- Milling/Screening

- Packaging

- Pre-Blending

- Spray Drying

- Tableting

- Terminal Sterilization

- Wet Granulating

Appendix B - List of Equipment Types

Enter one of the following Equipment Types in the Equipment Type field. Use suggested descriptors below each equipment type in the equipment Description.

- Air Jet Mill
Equipment Name, Mill Type, Size, Air Pressure, Nozzle Type, Nozzle Angle, Throughput (Kg/min.)

- **Autoclave**
Equipment Name, Chamber Size, Gravity / Vacuum, Manual / Electromechanical, Time, Temperature, Pressure, Indicator type, Indicator Results

- **Ball/Rod Mill**
Equipment Name, Mill type, Size, Rotation Speed, Mill Media, Mill Surface, Mill time, Mill type, Throughput (Kg/min.)

- Cone Mill
Equipment Name, Size, Screen Size, Rotor Type, Rotor Speed, Mill type, Feeder Type, Throughput (Kg/min.)

- Dry Granulator
Equipment Name, Size, Roll Type, Roll Speed, Roll Pressure, Roll Temperature, Feeder Type, Feed Rate

- **Encapsulator**
Equipment Name, Type, Filling Rate, Filling Type

- **Fluid Bed Dryer**
Equipment Name, Size, Temperature of Air, Dryer Type, Load (Kg), Drying Time (hr), Air Vol./Veloc.

- Fluid Bed Granulator/Dryer
Equipment Name, Size, Air Volume/Velocity, Spray Rate/Time, Temperature of Air, Granulator Type, Load (Kg), Conc. % Solids, Volume (L), Method of Addition, Nozzle Type, Nozzle Position, Nozzle Air Pressure

- **Fluid Bed Wurster Coater**
Equipment Name, Size, Spacer Height, Dispersor Plate Type, Temperature of Air, Coating Equipment Type, Spray Nozzle Used, Air/Airless, Pump Used, Coating Setup

- Hammermill
Equipment Name, Air Swepted, Temperature Control, Blade Orientation, Blade Type, Screen Type or No., Screen Open Area, Screen Opening Size (microns), Rotor Speed (RPM), Feeder Type, Throughput (Kg/min.)

- High Shear Mixer
Equipment Name, Agitator Speed/Timing, Chopper Speed/Timing, Jacket Temp (C), Mix Time (Total Min.), Size, Granulator Type, Load (Kg), Solution Used/Quantity, Gran. Fluid Temp (C), Gran. Fluid Volume (L), Method of Addition (Binder), End Point Detection

- **Liquid Granulator**
Equipment Name, Mixer Type, Mix Time (Total Min.), Load (Liters), Procedure, Temp (C), Agitation Rate

- **Non-Perforated Coating Pan**
  Equipment Name, Size, Coating, Solution Used, Pan Speed Start, Spray Rate, Temperature of Air, Coating Equip type, Spray Nozzle Used, Air/Airless, Method of Liquid Addition, Coating Setup

- Oscillating Granulator
  Equipment Name, Rotor Speed (RPM), Screen Type or No., Screen Opening Size (microns), Feed System, Throughput (Kg/min.), Size

- **Packaging Equipment**
  Equipment Name, Filler/Counter Type, Capper Type

- **Perforated Pan Coater**
  Equipment Name, Mix Time (Total Min.), Pan Speed Start, Perforation Size (mm), Size, Solution Used, Spray Nozzle Used, Air/Airless nozzle, Spray Rate (ml/min.), Spray Pressure, Inlet temperature, Outlet Air Temp, Heater Temp. (F), Pan load, Coating setup, Flap %

- Planetary Granulator
  Equipment Name, Blade Type, Mix Time, Solution Used/Quantity, Rotation Speed, Size, Load, End Point

- Ribbon Mixer
  Equipment Name, Ribbon Type, Mix Time, Shifter (Y/N), Rotational Speed, Size, Load, Order of Addition

- Screening
  Equipment Name, Screen Type or No., Screen Setup, Feed System/Rate

- Sigma Blade Granulator
  Equipment Name, Blade Type, Mix Time, Solution Used/Quantity, Rotation Speed, Size, Load, End Point

- Tablet Press
  Equipment Name, Feeder Type, No. of Punches, Press Speed, Precompression used (Y/N), Tablet Rate

- **Tray Dryer - Drying**
  Equipment Name, Air Flow Pattern, Drying Temp (C), Size, Tray Load (Kgm), Inlet Temp (C), Drying Time (hr), Air Vol./Veloc.

- Tumble Granulator Dryer
  Equipment Name, Jacket temp (C), Solution Used/Quantity, Method of Addition (Binder), Granulation Time (Total), Liquid Addition Time (Total), Rotation Speed (RPM), Size, Dryer Type, Load (Kg), Drying Time (hr), Pressure (mmhg), Air Purge

- Tumble Mixer - Dry Blending
  Equipment Name, Dispersator, Jacket temp (C), Mix Time (Total Min.), Rotation Speed (RPM), Size, Load, Blender Type, Order of Addition

- Tumble Mixer - Finished Blending
  Equipment Name, Dispersator, Jacket Temp(C), Rotation Speed(RPM), Size, Material Load Total, Blender Type, Load (Kg), Order of Addition, Lubricant Blend Time

- **Vacuum Pan Dryer**

  Equipment Name, Agitator Type, Agitator Speed (RPM), Pressure (mmHg), Size, Wall Temp, Dryer Type, Load (Kg), Drying Time (hr), Air Purge

- Other

  Equipment Name, Description, Comments